

Takeda gets FDA nod for three diabetes drugs

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Singapore: Japan-headquartered Takeda Pharmaceutical received the US Food and Drug Administration (FDA) approval for Nesina (alogliptin) and the fixed-dose combination (FDC) therapies Oseni (alogliptin and pioglitazone) and Kazano (alogliptin and metformin HCl) for the treatment of type 2 diabetes in adults as adjuncts to diet and exercise.

Nesina is a dipeptidyl peptidase-4 inhibitor (DPP-4i) that is designed to slow the inactivation of incretin hormones GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulintropic peptide). Oseni, which combines alogliptin with pioglitazone, is the first product in the US to include both a DPP-4i and a thiazolidinedione (TZD) in a single tablet. Kazano combines alogliptin with metformin HCl, a widely used anti-diabetes medication, in a single tablet.

US-based Takeda Global Research & Development Center conducted the worldwide placebo- and active-controlled clinical trials of Nesina involving more than 13,000 patients. The safety and efficacy of Nesina was studied as a once-daily monotherapy and in combination with several other classes of anti-diabetic medications, including biguanides, TZDs, insulin and sulfonylureas. In these studies, Nesina 25 mg, taken once daily, demonstrated clinically meaningful and statistically significant improvements in hemoglobin A1C compared to placebo.

Of the total number of patients included in the Nesina clinical trial program, more than 3,000 were included in the studies used to support the FDA approval of Oseni, and more than 4,000 were included in those to support the FDA approval of Kazano. Study results indicated that alogliptin co-administered with either pioglitazone or metformin HCl produced significant improvements in glycemic control as compared to the respective monotherapies.

"Takeda is pleased with the FDA approval of Nesina, Oseni and Kazano for the treatment of type 2 diabetes, a therapeutic category in which we have more than twenty years of clinical and patient experience," said Mr Douglas Cole, president of the US subsidiary of the company. "Millions of people are affected by diabetes and, as a leader in the diabetes arena, Takeda is dedicated to working to advance patient care and helping to meet the needs of this growing patient population."

Type 2 diabetes is the most common form of diabetes affecting millions of people globally. According to the International Diabetes Federation, the global health care expenditures for diabetes (both type 1 and 2) were estimated at \$471.6 billion in 2012. By 2030, this number is projected to exceed \$595 billion. In fact, more than 23 million people in the US alone currently

live with the disease. Type 2 diabetes is a progressive and chronic condition and patients should work with a health care professional to manage and monitor their disease. In addition to diet and exercise, patients often need to take multiple medications in order to help them manage their blood glucose levels.